

Pharmacopoeia since it contained a substantial amount of unidentified dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: Maizel Laboratories, Inc., claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories to which claimant objected in part. After a hearing, the claimant was required to answer all of the interrogatories but eight. Subsequently, the Government filed additional interrogatories which claimant answered. Thereafter, claimant having consented, on 8-10-59, a decree of condemnation was entered and the article was destroyed.

6004. Enerjol capsules. (F.D.C. No. 41276. S. Nos. 85-201/4 M.)

QUANTITY: 5,213 btl. of double strength capsules, and 2,733 btl. of single strength capsules, at Chicago, Ill., in possession of Owen Laboratories.

SHIPPED: 11-18-57 and 12-5-57, from Long Island City, N.Y.

LABEL IN PART: "60 (or other number) Capsules Lot No. 30019 ENERJOL DOUBLE STRENGTH Each Capsule contains: Thiamin Chloride 20 mgm. Riboflavin 10 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 10 I. U. Vitamin B-12 Cobalamin conc. 10 mcgm. Iron (from ferrous gluconate) 20 mgm. Oyster Shell Powder 25 mgm. Royal Jelly 25 mgm. Iodine (from potassium iodide) 0.2 mgm. For use as a Dietary Supplement: One capsule daily." or "SINGLE STRENGTH Each capsule contains: Thiamin chloride 10 mgm. Riboflavin 5 mgm. Vitamin E (as D-alpha tocopherol acid succinate) 5 I. U. Vitamin B-12 Cobalamin conc. 5 mcgm. Iron (from ferrous gluconate) 10 mgm. Oyster Shell Powder 20 mgm. Royal Jelly 12.5 mgm. Iodine (from potassium iodide) 0.1 mgm. For use as a dietary supplement."

ACCOMPANYING LABELING: Circulars entitled "Owen Laboratories. The Enerjol Plan With Royal Jelly The Queen Bees Answer to Long Life" and "Discovered: New Wonder Capsule so Potent It Actually 'Combats Ills of Old Age' * * * Helps Put back Power Into Important Bodily Functions."

LIBELED: 12-9-57, N. Dist. Ill.; libel amended 12-19-57.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for glandular diseases, tiredness, sexual deficiency, nervous tension, dizziness, lack of sleep, loss of mental and physical ambition, lack of appetite, increasing longevity, and weakened, tired eyes; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: Owen Laboratories appeared as claimant and filed an answer denying that the drug was misbranded or a new drug. Thereafter, the Government filed written interrogatories against the claimant. On 4-30-58, the claimant requested additional time to answer the interrogatories, which was granted. Thereafter, on 5-8-58, the claimant filed objections to the interrogatories. Subsequently the Government filed a motion to have the objections stricken since additional time had not been granted for claimant to object to the interrogatories. The court thereupon, on 5-21-58, ordered that the

objections to the interrogatories be stricken. The court further ordered, on 5-26-58, that the interrogatories be answered.

On 6-4-58, the claimant then filed a motion to dismiss and for summary judgment. The court, on 9-8-58, entered the following memorandum opinion denying the claimant's motion to dismiss and for summary judgment:

SULLIVAN, *District Judge*: "This is a libel of information brought by the Government under Title 21 U.S.C. § 334, for the condemnation of certain bottles of a drug called 'Enerjol.' The condemnation is sought on the grounds that the contents of the bottles are misbranded under Sec. 352(a), and that 'Enerjol' is a 'new drug' under Section 355(a), as to which no effective application has been filed under Section 355(b).

"The claimant has moved to dismiss the libel and for a summary judgment. The sole basis for the motion is that in September, 1957, claimant entered into an agreement with the Post Office Department in an action brought against claimant by that Department under the provisions of Title 39 U.S.C. Sections 259 and 732, and allegedly concerned with the same product and same labels as those here involved. It is claimant's position that in view of the former proceedings, and the agreement, the present libel subjects claimant to a 'multiplicity of actions' and 'unjust harassment,' and that the agreement in the post office action is a bar 'in effect akin to the legal principles of *res adjudicata*.'

"The last argument is clearly in error. The doctrine of *res adjudicata* applies only when there has been an actual adjudication of the same issues in a prior proceeding. (*United States v. International Building Co.*, 345 U.S. 502, 505(1953)). Such is not the case here. In the Post Office proceeding, the issue was actual intent to deceive by means of false or of fraudulent pretenses (*Reilly v. Pinkus*, 338 U.S. 276(1949)). Here, the issue is whether the article is misbranded. It is settled in this Circuit that 'the offense of using the mails to defraud and the offense of introducing or delivering for introduction into interstate commerce misbranded drugs are not the same, and hence there is no *res judicata*.' (*United States v. Kaadt*, 171 F. 2d 600, at 605 (7th Cir. 1949); see also *United States v. 42 Jars*, etc. 160 F. Supp. 818, 821 (D.N.J. 1958).

"Claimant argues that he is not contending that the traditional doctrine of *res adjudicata* applies, but that something 'akin' to it is involved. This argument also must fail. However far one might stretch the traditional doctrine, it must at least involve some form of prior adjudication definite enough to form a standard against which the current action can be measured. In the instant situation there was no adjudication of any sort in the Post Office action. The agreement (attached to the motion) shows that claimant there merely agreed to refrain from making certain representations in the future. If this amounts to anything, it is an admission by claimant against his interests in this suit. Finally, the agreement provides that it 'will not act as a defense for violation of any other statute.' This in itself should preclude its use here.

"The argument that claimant is being subjected to 'multiplicity of actions' and 'undue harassment' is a specious one. It is perfectly apparent that the purposes and effect of the Post Office action and one for condemnation are entirely different and that the two remedies are properly distinct and co-existent. (*United States v. One Dozen Bottles*, 146 F. 2d 361, 363 (4th Cir., 1944)).

"For the foregoing reasons, the motions to dismiss and for a summary judgment are denied."

On 10-8-58, the Government filed a motion for entry of default decree since the claimant had failed to answer the interrogatories as ordered by the court. A default decree of condemnation was entered on 10-22-58. The claimant then filed notice of appeal to the United States Court of Appeals for the Seventh Circuit. On 3-31-59, the court of appeals handed down the following opinion affirming the judgment of the district court (265 F. 2d 332):

HASTINGS, *Circuit Judge*. "The Government, libelant-appellee, brought this action under the provisions of the Federal Food, Drug and Cosmetics Act, 21 U.S.C.A. §§ 301 et seq., for the condemnation and seizure of a drug called 'Enerjol.' The corporate claimant, Owen Laboratories, Inc., refused to answer the libelant's interrogatories on the ground of self-incrimination and the district court thereupon entered a default decree of condemnation. This appeal is taken from that decree and from an order of the district court denying claimant's motion for dismissal of the libel and for summary judgment.

"The instant suit was commenced in December of 1957. The amended libel charged that the drug, 'Enerjol,' was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C.A. § 352(a), and also alleged that the drug was a 'new drug' which was introduced into interstate commerce without an effective new drug application as provided in 21 U.S.C.A. § 355 (a) and (b).

"Prior to this action, in September of 1957, the Post Office Department had issued a fraud complaint against Owen Laboratories, Inc., charging it with having obtained money through the mails by means of fraudulent representations regarding the nature of and benefits to be obtained from the so-called 'Enerjol Capsules.' In order to avoid having a fraud order entered against it, Owen Laboratories filed an 'Affidavit of Agreement' in which it consented to cease making the representations charged to be fraudulent in the Post Office complaint.

"Claimant moved for a dismissal of the instant suit and for summary judgment, on the ground that the agreement with the Post Office, entered into after initiation of the mail fraud proceeding, was, in effect, an adjudication¹ with respect to the identical product, the identical literature and identical issues involved in this libel; and that the agreement 'constitutes a bar to the present action and is in effect akin to the legal principle of *res adjudicata*.' The district court denied this motion setting forth its reasoning in a brief memorandum opinion which indicates that it fully understood and rejected claimant's arguments made before that court and renewed in this appeal. We hold that the district court committed no error in denying this motion.

"The mail fraud proceeding could not possibly be a bar to the instant action. In the first place, the agreement executed by claimant in connection with the mail fraud proceeding is, by its own express terms and contrary to claimant's contentions, not an approval or ratification of any business conducted or to be conducted by claimant. The agreement further states expressly that 'its filing will not act as a defense or relieve the undersigned [claimant's president] of responsibility for violation of any other statute * * *.'

"Further, when stripped of its refinements, claimant's position appears to be that the Postmaster General, with his limited authority under the mail fraud statutes, could and should have somehow effectively enforced the provisions of the Federal Food, Drug and Cosmetics Act; and that, since he did take some action, as evidenced by the agreement, the Government is now barred from enforcing that Act against the offending product.

"Viewing claimant's contentions in this light merely points up the fact that the proceeding under the mail fraud statute and the instant one differ not only as to issues involved, but also as to purpose and effect. The Postmaster General has only the limited authority to prohibit the fraudulent use of the mails, and the sole purpose of a mail fraud proceeding is to enjoin the continuation of conduct found fraudulent. *Donaldson v. Read Magazine, Inc.*, 333 U.S. 178, 191 (1948). There must be proof of a fraudulent purpose, an actual intent to deceive, on the part of the alleged violator. *Reilly v. Pinkus*, 338 U.S. 269, 276 (1949).

"On the other hand, the present suit under the Food, Drug and Cosmetics Act has as its purpose the seizure and actual removal of the allegedly offending articles from the channels of trade. Under this Act, no proof of wrongful or fraudulent intent is required either in criminal proceedings brought under its provision, *United States v. Dotterweich*, 320 U.S. 277, 281, 284-285 (1943), or in seizure cases such as the instant one. *Research Laboratories v. United*

¹ By "adjudication" claimant refers to any type of administrative action. It argues extensively in its brief for the adoption by this court of a new rule of "res administrata" embodying principles "akin to the legal principle of *res adjudicata*" but tailored to fit problems peculiar to administrative law.

States, 9 Cir., 167 F. 2d 410, 420-421 (1948); *United States v. Five Cases, etc.*, 2 Cir., 156 F. 2d 493, 495 (1946). The Supreme Court in *Dotterweich* pointed out that by this Act, as amended in 1938:

* * * Congress extended the range of its control over illicit and noxious articles * * *. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self protection. * * * In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." *United States v. Dotterweich*, *supra* at 280-281.

In the libel in this case the drug is alleged to be subject to seizure not only as misbranded (falsely labeled) but also as a new drug introduced into interstate commerce without an effective new drug application to establish its safety as is required by law. The proceeding and resulting agreement under the mail fraud act could be no bar to this suit.

"Reliance by claimant on *United States v. Willard Tablet Co.*, 7 Cir., 141 F. 2d 141 (1944) is misplaced. In that case, a prior decision by the Federal Trade Commission had *approved* statements used by an alleged violator and ruled that the statements were not false representations. We held that a subsequent condemnation proceeding, under the Federal Food, Drug and Cosmetics Act based on identical statements as to the same product was barred, on principles of *res adjudicata*, because the same issues and elements of proof were involved in both proceedings. The case of *George H. Lee Co. v. Federal Trade Commission*, 8 Cir., 113 F. 2d 583 (1940) also cited by claimant is to the same effect.

"Claimant also relied heavily, in its brief, on the case of *United States v. Radio Corporation of America and National Broadcasting Company, Inc.*, E.D. Pa., 158 F. Supp. 333 (1958). In that case the district court decided that approval by the Federal Communications Commission of a proposed exchange of radio and television stations, precluded a subsequent suit in which the Government sought to upset the transaction as violative of the anti-trust laws. However, just prior to oral argument in the present case, the Supreme Court of the United States, having noted probable jurisdiction at 357 U.S. 918 (1958), unanimously reversed the district court. *United States v. Radio Corporation of America and National Broadcasting Company, Inc.*, . . . U.S. . . . (1959).² The Supreme Court held that the Federal Communications Commission had no power to decide anti-trust issues as such and that, consequently, its determination that the 'public interest, convenience and necessity' would be served by the proposed exchange of radio and television stations did not bar the subsequent anti-trust suit. In so doing the Court found *res judicata* principles inapplicable since, as in the instant case, different issues were involved. *Id.* at . . . In our view, this holding alone would be completely dispositive of claimant's contention.

"It is next contended that the district court erred in entering the default decree of condemnation upon claimant's failure to answer libellant's interrogatories. The refusal of the corporation to answer was based on an assertion of a claim of privilege against self-incrimination. However, it is settled beyond possible doubt that a corporation has no such privilege to assert. *United States v. White*, 322 U.S. 694 (1944). In the *White* case, the Supreme Court stated clearly and unequivocally:

The constitutional privilege against self-incrimination is essentially a personal one applying only to natural individuals.

* * * [I]t cannot be utilized by or on behalf of any organization, such as a corporation. (Emphasis added.) (*id.* at 698-699).

See also *Fleming v. Montgomery Ward*, 7 Cir., 114 F. 2d 384, 386-387 (1940), cert. den., 311 U.S. 690.

"In the face of this, claimant urges that a corporation may somehow assert the privilege against self-incrimination on behalf of itself, and a broad class of corporate officers and agents, because of what it terms the unique

² Mr. Justice Frankfurter and Mr. Justice Douglas took no part in the consideration or decision of the case.

nature of the Federal Food, Drug and Cosmetics Act which imposes criminal liability on officers and agents of the corporation without requiring proof of wrongful intent or consciousness of wrongdoing.

"It is true that this Act is an example of the so-called 'public welfare statute' which requires no proof of wrongful intent. *Morissette v. United States*, 342 U.S. 246, 255-256 (1952); *United States v. Dotterweich*, 320 U.S. 277 (1943). However, criminal liability is not, as claimant seems to contend, imposed automatically under this type of law upon every officer or agent no matter how remote his connection with the offending corporation. In *Dotterweich*, the Supreme Court clearly enunciated the proper test. Criminal responsibility for violation of the Federal Food, Drug and Cosmetics Act attaches to those who have a responsible share in the furtherance of the transaction which the statute outlaws. 'Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under proper guidance.' (Emphasis added.) *U.S. v. Dotterweich*, *supra* at 284.

"It was the duty of this corporate claimant to select an agent who, without fear of self-incrimination, could provide the information requested. The interrogatories were addressed to the corporation and the answer sought was that of the corporation. There is no merit in claimant's suggestion that the answers to the interrogatories must be verified by an officer or managing agent of the corporation. Rule 33 of the Federal Rules of Civil Procedure, 28 U.S.C.A., provides that 'any officer or agent' of a corporate party 'shall furnish such information as is available to the party.' It would indeed be incongruous to permit a corporation to select an individual to verify the corporation's answers, who because he fears self-incrimination may thus secure for the corporation the benefits of a privilege it does not have.

"The default decree was entered by the district court pursuant to Rule 37(d) F.R.C.P., 28 U.S.C.A., which provides:

If a party or an officer or managing agent of a party wilfully fails to appear before the officer who is to take his deposition, after being served with proper notice, or fails to serve answers to interrogatories submitted under Rule 33, after proper service of such interrogatories, the court on motion and notice may * * * enter a judgment by default against the party.

Claimant asserts that there was no wilful failure to answer since the officer of the corporation, in this case the president, properly asserted his constitutional privilege against self-incrimination even if the corporation had no such privilege. We have answered this contention above. Claimant had a duty to appoint an agent who could, without fear of self-incrimination, furnish such requested information as was available to the corporation. No attempt was made to do so.

"The disjunctive wording of the rule, above, would seem to indicate that a showing of wilfulness is necessary only on failure to appear for deposition. Assuming that such is not the case, however, we hold that what is intended by 'wilful failure' to comply with the rule is any intentional failure as distinguished from involuntary noncompliance. No wrongful intent need be shown. *Brookdale Mill Inc. v. Rowley*, 6 Cir., 218 F.2d 728, 729 (1954).

"But beyond that, we are singularly unimpressed with claimant's arguments, in view of the following statement made by claimant's president in an affidavit accompanying the motion to dismiss and for summary judgment: 'I have not made any false or improper claims in connection with the marketing of this product. My products are marketed based upon extensive research and consultation with experts.' Thus, though first representing to the court that it had such information available and implicitly offering it in support of this motion, when it was later served with interrogatories seeking details of such 'extensive research and consultation,' claimant asserted its claimed privilege.

"Finally, *Societe Internationale v. Rogers*, 357 U.S. 197 (1958) relied on by claimant is inapposite since in that case the Supreme Court felt that dismissal under Rule 37 was too harsh a remedy where there was evidence of a good faith effort to comply with the rule. No attempt was made to comply in this case.

"We hold that the trial court did not err in entering the default decree upon proper motion by the Government and notice to claimant.³

"The judgment and decree of condemnation is AFFIRMED."

Thereafter, the claimant filed a petition for writ of certiorari with the United States Supreme Court, which petition was denied on 6-29-59 (360 U.S. 931). The article and the accompanying circulars were subsequently destroyed in accordance with the terms of the decree of condemnation.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6005. Tranquil. (F.D.C. No. 3987L S. Nos. 60-309 M, 60-361 M.)

QUANTITY: 317 btls. at Detroit, Mich.

SHIPPED: 12-26-56 and 1-25-57, from Chicago, Ill., by State Pharmacal Co.

LABEL IN PART: "Tranquil * * * Alva Laboratories * * * Active Ingredients:

Each Tranquil contains in grams: Scopolamine Aminoxide Hydrobromide .00010; Methapyraline Hydrochloride N. N-Dimethyl-N'(2 Phenyl)-N'(2-Pyridyl)-Ethylenediamine Hydrochloride; Bromides; Sodium .09700, Potassium .19400, Ammonium .03285; Niacin; Niacinamide; Thiamine Hydrochloride; Riboflavin; Cyanocobalamin; Stomach and Liver whole desiccated (containing entire B Complex); Ferric Pyrophosphate, Acetanilid .05000; * * * Tranquil is Multiaction and embodies recent scientific developments in reducing nervous tension."

ACCOMPANYING LABELING: Leaflet in each bottle entitled "TRANQUIL—An aid in relief of nervous tension"; leaflets for druggists entitled "MR. DRUGGIST"; and display cartons reading in part: "Safe TRANQUILIZING AID."

LIBELED: 2-15-57, E. Dist. Mich.; amended libel 6-8-59.

CHARGE: 502(a)—when shipped, the name of the article "*Tranquil*" and the labeling of the article contained false and misleading representations that the article was one of the recently developed "tranquilizing" drugs and that it would produce all of the effects capable of being produced by a true "tranquilizer" drug; 502(c)—the ingredient statements required by 502(e)(2), and the warnings required by 502(f)(2), to appear in the labeling of the article were not prominently placed thereon with such conspicuousness and in such terms, as to render the required ingredient statements and warnings likely to be read and understood by the ordinary individual under customary conditions of purchase and use; 502(f)(2)—the labeling of the article failed to warn that frequent or continued use of the article may cause serious blood disturbances and mental derangement, and that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon the advice of a physician; and 503(b)(4)—the article was a drug sub-

³ In their briefs both parties refer to *United States v. 42 Jars, etc.* * * * *Bee Royale Capsules*, D.C.D. N.J., 160 F. Supp. 818 (1958) and 162 F. Supp. 944 (1958), and note an appeal pending therefrom in the Third Circuit. In an opinion filed March 12, 1959, the Court of Appeals for the Third Circuit affirmed, deciding the issues identical to those considered in the instant appeal agreeable with the result reached in this opinion, viz: that the action taken by the Post Office Department upon its fraud complaint and subsequent settlement was no bar to the action brought under the Federal Food, Drug and Cosmetics Act, (thus rejecting the proposed rule of "*res administrata*," see note 1, *supra*); that the corporate claimants could not resort to the Fifth Amendment as a basis for refusing to answer interrogatories, and that it was within the trial court's discretion to enter a default judgment under Rule 37(d), F.R.C.P., 28 U.S.C.A., by reason of such failure to answer. Thus, we find ourselves in complete agreement with the Third Circuit although, in our consideration and determination of this case we did not have the benefit of its prior holding.